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Outcomes Assessment

Migraine

Prepared for Kansas Medicaid in August, 2008

EXECUTIVE SUMMARY

Purpose of Intervention	To improve the pharmacotherapy of migraine headache by promoting the most clinically appropriate and cost-effective therapy for headache prevention and acute treatment.

Intervention	Intervention Type	Population-based mailing
	Intervention Mailing Date	October 2007
	Pre-intervention Period (Baseline)	April 2007 – September 2007
	Post-intervention Period (Post)	November 2007 – April 2008
	Number of Letters Mailed	140
	Number of Targeted Physicians	140
	Number of Targeted Patients	138
	Adjusted Targeted Patients	71

Changes in Clinical Indicators

Clinical Indicators	Baseline	Target Apr-08	% Change
Overutilization	36	26	-27.8%
Increased Risk of ADE	21	8	-61.9%
Underutilization	8	3	-62.5%
Medication Non-Compliance	8	5	-37.5%
Duplicate Therapy	1	1	0.0%
Total	74	43	-41.9%

Savings Calculation

Intervention-Related Pharmacy Savings	
Targeted Group: Actual Average Paid Amount Per Patient Per Month (Baseline)	$382.49
Targeted Group: Actual Average Paid Amount Per Patient Per Month (Post)	$372.80
Estimated Savings Per Patient Per Month	$9.69
Total Number of Targeted Patients	71
6-Month Total Savings	$4,129.52

Intervention-Related Medical Savings	
Targeted Group: Actual Average Paid Amount Per Patient Per Month (Baseline)	$124.34
Targeted Group: Actual Average Paid Amount Per Patient Per Month (Post)	$36.15
Estimated Savings Per Patient Per Month	$88.19
Total Number of Targeted Patients	71
6-Month Total Savings	$37,567.08

BACKGROUND

Migraines interfere with the activities of daily living; they decrease physical activity and appetite and increase fatigue and sensitivity to light and sound. Migraine frequency varies from as few as one to more than 10 attacks per month. They can be very debilitating, resulting in days lost from work and school. This costs our society at least $5 billion in lost productivity and 270 lost workdays for every 1000 workers each year.[1] The disability incurred by this disorder was rated in a recent survey by the World Health Organization (WHO), which concluded that a day with severe migraine is as disabling as a day with quadriplegia.[2] Migraine takes an enormous social and economic toll on the individual and on society as a whole.

There are more than 200 different prescription and nonprescription migraine medications available in a variety of dosage forms (oral, intranasal, injectable, and rectal). Unfortunately, monotherapy does not always provide rapid, consistent, and complete relief in all migraineurs.[3] Therefore combination therapies may be necessary to treat each patient's specific migraine signs and symptoms. A rational approach to migraine management includes providing patients with preventive therapy where indicated and evaluating quality of care issues for acute and adjunctive drug therapy as well as preventive regimens. It is also necessary to minimize or eliminate overuse, misuse and abuse of those drugs that have potential for physical and/or psychological dependence. The American College of Physicians, American Society of Internal Medicine, and American Academy of Family Physicians recommend use of nonsteroidal anti-inflammatory drugs (e.g. ibuprofen) and aspirin for migraines, after symptoms have developed.[4] This consortium of physicians supports the use of triptans, but warns of their associated serious adverse events in patients with heart disease, high blood pressure, and nerve weakness. Use of narcotics for migraines is supported by few studies and patients can become addicted to these agents.

Additionally, inappropriate use of migraine medication may contribute to the development of chronic headaches which is refractory to most treatments.[5] Daily use of antipyretic or anti-inflammatory analgesics, opioids, ergot alkaloids, and triptan therapy can result in chronic daily headache. Headaches that become chronic due to utilization of daily pain medication will vanish or improve with abstinence from the pain medication. In these cases, treatment includes drug withdrawal followed by structured acute therapy and initiation of migraine prophylaxis treatment. The literature supports use of preventative therapies for migraines in patients who get two or more migraines per month, have severe migraine symptoms three or more days per month, use drugs to treat migraine more than twice per week, do not benefit from migraine treatment, or have migraine complicated by neurologic symptoms.[4]

The overall objective of migraine management should be: 1) prevention to reduce attack frequency and severity; 2) improved responsiveness, including minimal side effects, to treatment of acute attacks; 3) avoidance of migraine medication overuse; and 4) patient education and empowerment on disease management.[3,6]

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[1] APhA Special Report. Self-Treatment of Migraine and Other Types of Headache. American Pharmaceutical Association. 1998.
[2] Goadsby PJ, Lipton RB, Ferrari MD. Migraine-Current Understanding and Treatment. N Engl J Med 2002; 346(4):257-270.
[3] Peroutka SJ. Beyond Monotherapy: Rational Polytherapy in Migraine. Headache 1998; 38:18-22.
[4] Snow V, Weiss K, Wall EM, et al. Pharmacologic management of acute attacks of migraine and prevention of migraine attacks. Ann Intern Med 2002;137:840-849.
[5] Kavuk I, Katsarava Z, Selekler M, et al. Clinical features and therapy of medication overuse headache. Eur J Med Res 2004 Dec 22;9(12):565-9.
[6] The US Headache Consortium: Evidence-Based Guidelines for Migraine Headache in the Primary Care Setting: Pharmacological Management for Prevention of Migraine. American Academy of Neurology; 2000.

METHODOLOGY

Changes in intervention-related pharmacy dollars paid, pharmacy dollars paid per patient per month (PPPM), and number of pharmacy claims were examined. This intervention identified providers whose patients were affected by overutilization, increased risk of ADE, underutilization, medication non-compliance, and duplicate therapy. To assess the impact of the intervention, pharmacy drug claims were reviewed from November 2007 through April 2008.

Clinical Criteria: Criteria, rationale, and text message(s) to providers are listed below. All physicians with at least one recipient "hitting" on criteria received letters.

- Overutilization

The overutilization indicator identifies migraineurs receiving acute migraine therapy, including 5 HT agonists, ergot derivatives, ergot/caffeine compounds and multi-ingredient analgesic compounds, such as Midrin and Fioricet and receiving acute and adjunctive therapy.

Rationale: Acute migraine therapy consists of a variety of pharmacologic classes of therapy. If acute therapy is overused, i.e., if the duration of use exceeds a specified number of days for the drug class, the migraineur may experience severe adverse effects or medication-overuse headaches (drug induced headaches). Adjunctive migraine therapy is used with acute therapy to provide additive analgesic effectiveness, to lessen the nausea and vomiting associated with the migraine, to promote absorption of specific acute therapies, to provide mild sedation and relaxation, or to break the event of an intractable headache. The duration of adjunctive therapy should be limited to allow full clinical benefits but discourage long-term use, which may predispose the migraineur to adverse events or possible physical dependence.

Sample Provider Paragraph:

POTENTIAL OVERUTILIZATION OF ERGOTS:
According to submitted pharmacy claims, it appears that your patient may be using an ergot agent excessively for migraine headache relief. This type of utilization can increase the risk of adverse drug events and may lead to rebound or worsening of headaches. Please review the use of this acute migraine therapy with your patient, discuss avoidance of migraine triggers and consider the addition or optimization of migraine preventive therapy.

- Increased Risk of ADE

The duplicate therapy indicator identifies migraineurs receiving acute migraine therapy.

Rationale: Patients receiving acute therapy, quality of care issues such as drug interactions and risk of adverse drug events should be monitored to promote optimal use of medications used to severity and duration of headache attacks.

Sample Provider Paragraph:

DRUG-DISEASE CONTRAINDICATION: 5-HT AGONISTS (TRIPTANS) & ISCHEMIC HEART DISEASE
Use of triptans is contraindicated in patients with ischemic heart disease due to the increased risk of coronary vasospasm. Please review the need for this medication and select an alternative agent.

- Underutilization
  Patients with migraine (inferred or ICD-9 documented), who have received acute migraine therapy within the last 90 days, that may qualify for preventive migraine therapy based on quantities submitted.

  Rationale: Preventive therapy for migraineurs can reduce the frequency of acute migraine attacks or the intensity and duration of the acute attack. Some medications used to treat other disease states, such as depression, hypertension, or seizures, are effective for preventing migraine. Through headache prevention, the need for acute treatment can be reduced and patient quality of life is improved.

  Sample Provider Paragraph:

  > Migraine & Insomnia or Depression: Consider comorbidity if prescribing preventive therapy (e.g., consider the use of an antidepressant such as amitriptyline or an SSRI, if appropriate).

- Medication Compliance
  Migraineurs receiving preventive migraine therapy will be identified. A 90-day window will be examined for gaps in therapy. To eliminate from consideration patients who stopped therapy, and/or switched to another drug, patients who did not receive the study drug in the 45-day window before and after the 90-day window will be excluded from analysis.

  Rationale: Noncompliance with prescribed preventive therapy can result in increased frequency of acute attacks or can erroneously lead the clinician to believe that the patient requires a higher dose or change in therapy to achieve adequate symptom control.

  Sample Provider Paragraph:

  > Your patient may be non-compliant with a medication used for migraine prevention. From prescription data, it appears that your patient received < 60 days of maintenance therapy in a 90 day period. Please review this information to determine the best course of action for your patient.

- Duplicate Therapy
  Migraineurs receiving analgesic adjunctive therapy.

  Rationale: The drug therapies used for analgesic adjunctive therapy in migraine have the potential for causing physical dependence and addiction. Use of these adjunctive drugs should be subject to review for patterns of use, which may reflect abuse or misuse of strong analgesics. Among the issues which may reflect inappropriate usage patterns are: excessive quantities being dispensed; drugs obtained from multiple prescribers and dispensed by multiple pharmacies; and therapeutic duplication or use of multiple analgesics from the same or similar therapeutic category.

  Sample Provider Paragraph:

  > MIGRAINE: CONCURRENT USE OF BUTORPHANOL & ADJUNCTIVE OPIATE ANALGESICS.
  > Use of butorphanol in patients taking an opiate analgesic chronically can precipitate a withdrawal syndrome. Please review the need for these medications and consider appropriate alternatives.

Definitions:

Adjusted Target Patients – All patients of physicians who were included in the intervention, who had pharmacy claims and were active plan members throughout the post-intervention time period. Additionally, when outcomes are performed, these patients' pre-intervention (baseline) hits are re-evaluated to make certain that the status of clinical indicators haven't changed for each patient due to late pharmacy and medical claims.

Intervention-Related Pharmacy – Ketoconazole, antidepressants: MAOI, antiparkinson: MAOI, serotonin antidepressants, migraine FTE: adjunct-analgesics, migraine FTE: adjunct-NV, migraine FTE: acute, nitrates, hydrocodone antitussives, migraine prevention: grp 1 and 2, macrolides, sibutramine, compliance: HTN meds, protease inhibitors, bromocriptine

Intervention-Related Medical – Migraine, ischemic heart disease, uncontrolled hypertension, cerebrovascular vascular disease, hepatic impairment, liver disease (chronic) & cirrhosis, chronic renal impairment, renal failure assc w/HTN, ischemic bowel disease, PVD, atherosclerosis, angina pectoris, HX MI, silent ischemia, porphyria, glaucoma: closed angle, insomnia, depressive D/O: major, depressive D/O: NEC, neurotic depression, hypertension, asthma, epilepsy, bipolar affective disorder.

RESULTS

Characteristics

Table 1 describes the patient populations for the target group included in the population-based intervention based upon mean age, gender, number of providers, average number of prescriptions per patient per month, and total drug utilization. As can be seen from the table, the target group was 45 years old on average, saw 4.9 providers, and utilized 11.9 prescriptions in the baseline period.

Table 1: Patient Characteristics

	Target (N=71)
Mean Age	44.5
Percentage Male	9.9%
Percentage Female	90.1%
Number of Providers	4.9
Average Number of Prescriptions PPPM*	11.9
Utilization of Intervention-Related Drugs**	
Average Number of Drugs***	5.2
Average Number of Claims	25.1
Average Days Supply	486.1
Average Amount Paid	$2,294.94

* Number of prescriptions per patient per month (PPPM) is the average for the 6 month baseline period

** Based on 6 months of baseline claims data

*** A distinct drug is defined by using a coding system similar to the Hierarchical Ingredient Code List (HICL) in that distinct drugs are identified at the ingredient level.

Overutilization

The changes in the number of patients with overutilization are displayed in Table 2. Overall, there was a reduction of 27.8% in the number of target patients.

Table 2: Changes in Overutilization

Overutilization	Target		
	Baseline	Apr-08	% Change
Overutilization Ergots	2	2	0.0%
Overuse of nausea and vomiting adjunctive tx	1	1	0.0%
Overutilization Triptan Therapy	30	20	-33.3%
>= 2 BOTTLES OF BUTORPHANOL PER MONTH	3	3	0.0%
Total	36	26	-27.8%

Increased Risk of ADE

The changes in the number of patients flagged for being at an increased risk of adverse drug events are displayed in Table 3. Overall, there was a 61.9% reduction in the number of target patients.

Table 3: Changes in Risk of ADE

Increased Riske of ADE	Target		
	Baseline	Apr-08	% Change
5-HT Agonists and Ischemic Heart Disease	2	0	-100.0%
5-HT and cerebrovascular disease	6	2	-66.7%
Migraine Med/Serotonin Antidepressant (SS)	13	6	-53.8%
Total	21	8	-61.9%

Underutilization

The changes in the number of patients flagged for underutilization of therapy are displayed in Table 4. Overall, there was a 62.5 % reduction in the number of target patients.

Table 4: Changes in Underutilization

Underutilization	Target		
	Baseline	Apr-08	% Change
Dx= Insomnia &/or Depression	2	1	-50.0%
Dx = Hypertension	3	1	-66.7%
Dx= Reactive Airway Disease	2	1	-50.0%
Dx= Seizures &/or Bipolar Disorder	1	0	-100.0%
Total	8	3	-62.5%

Medication Non-Compliance

Table 5 displays the changes in those target patients who were flagged for non-compliance. Overall, this indicator decreased by 37.5% in the target group.

Table 5: Changes in Non-compliance

Medication Non-Compliance	Target		
	Baseline	Apr-08	% Change
Prophylaxis Migraine Meds	8	5	-37.5%

Duplicate Therapy

Table 6 displays the changes in those target patients who were flagged for duplicate therapy. Overall, these indicators decreased by 37.5% in the target group.

Table 6: Changes in Duplicate Therapy

Duplicate Therapy	Target		
	Baseline	Apr-08	% Change
Concurrent butorphanal and adjunctive analgesics	1	1	0.0%

BUSINESS ANALYSIS

The overall savings for the intervention are calculated in Tables 7 and 8. Per patient per month (PPPM) drug amount paid for intervention-related drugs and intervention-related medical were separately calculated for the target group for the six-month baseline and six-month post-intervention periods. This percentage was then multiplied by the baseline PPPM amount paid for the targeted group in order to estimate the PPPM amount paid in the post-intervention period for the targeted group had there been no intervention. The actual PPPM amount paid for the targeted group was then subtracted to obtain the estimated PPPM savings. Finally, the PPPM savings was multiplied by the number of intervention months and number of targeted patients.

Table 7 shows the intervention-related drug amount paid for target patients decreased $9.69 in the post-intervention period. This yielded an overall estimated savings of $4,130 in intervention-related drug expenditures during the six-month post-intervention period.

Table 8 shows the intervention-related medical amount paid for target patients decreased $88.19 in the post-intervention period. This yielded an overall estimated savings of $37,567 in intervention-related medical expenditures during the six-month post-intervention period.

Table 7: Intervention-Related Pharmacy Savings

Savings Calculation:	
Targeted Group: Actual Average Paid Amount Per Patient Per Month (Baseline)	$382.49
Targeted Group: Actual Average Paid Amount Per Patient Per Month (Post)	$372.80
% Change in Target Group from Baseline to Post	-2.53%
Estimated Savings Per Patient Per Month	$9.69
Total Number of Targeted Patients	71
6-Month Total Savings	$4,129.52

Table 8: Intervention-Related Medical Savings

Savings Calculation:	
Targeted Group: Actual Average Paid Amount Per Patient Per Month (Baseline)	$124.34
Targeted Group: Actual Average Paid Amount Per Patient Per Month (Post)	$36.15
% Change in Target Group from Baseline to Post	-70.93%
Estimated Savings Per Patient Per Month	$88.19
Total Number of Targeted Patients	71
6-Month Total Savings	$37,567.08

LIMITATIONS

A control group was not utilized for this intervention. This limited the comparisons that could be performed in the analysis. Therefore, instead of being able to compare an intervention group with a non-intervention group, the analysis is essentially limited to changes in the intervention group before and after intervention.

The time frame of 6 months may not capture the full extent of the impact of the intervention. Providers may be required some time before they can change their patient's drug regimens. Additionally, if this study included only users of chronic medications, this may have more accurately reflected the pharmacy cost changes in both groups.

CONCLUSIONS

This intervention focused on improving prescribing practices and reducing the overall cost of care. Overall, the intervention was successful in reducing the total number of clinical indicators for target patients by 41.9%.

In terms of financial outcomes, the amount paid for intervention-related drugs decreased $9.69 in the post-intervention period. This yielded an overall estimated savings of $4,130 in intervention-related drug expenditures during the six-month post-intervention period. Also, the estimated paid amount per patient per month for intervention-related medical claims decreased $88.19 during the six-month post-intervention period. This yielded an overall estimated medical savings of $37,567 during the six-month post-intervention period. The total estimated savings due to the intervention was $41,697 during the six-month post-intervention period.